



DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG-2015-0090]

**Medical Waivers for Merchant Mariner Credential Applicants
with the following Conditions: Cardiomyopathy; Diabetes
Mellitus; Narcolepsy; and Obstructive Sleep Apnea**

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed policy clarification and
request for comments.

SUMMARY: The Coast Guard is seeking public comment on the policy clarification proposed in this document regarding the specific medical documentation the Coast Guard will consider in determining whether a medical waiver is warranted for merchant mariners with cardiomyopathy, diabetes mellitus, or obstructive sleep apnea. Additionally, the proposed policy clarification specifies that narcolepsy, idiopathic hypersomnia, and other hypersomnias of central origin, are medically disqualifying and generally not waiverable due to significant risk of sudden and unpredictable incapacitation of individuals who have these conditions.

DATES: Comments and related material must either be

submitted to our online docket via
<http://www.regulations.gov> on or before **[INSERT DATE 90
DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** or
reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket
number USCG-2015-0090 using any one of the following
methods:

(1) Federal eRulemaking Portal:

<http://www.regulations.gov>.

(2) Fax: 202-493-2251.

(3) Mail: Docket Management Facility (M-30), U.S.
Department of Transportation, West Building Ground Floor,
Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC
20590-0001.

(4) Hand delivery: Same as mail address above,
between 9 a.m. and 5 p.m., Monday through Friday, except
Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these
four methods. See the "Public Participation and Request
for Comments" portion of the **SUPPLEMENTARY INFORMATION**
section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions
about this document, call or e-mail Lieutenant Ashley Holm,
Mariner Credentialing Program Policy Division (CG-CVC-4),

U.S. Coast Guard, telephone 202-372-2357, e-mail MMCPolicy@uscg.mil. If you have questions on viewing material in the docket, call Docket Operations at 202-366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

You may submit comments and related material regarding whether the policy clarification proposed in this document should be incorporated into final policy on the medical evaluation guidelines for mariners with cardiomyopathy, diabetes mellitus, narcolepsy or obstructive sleep apnea. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting comments: If you submit a comment, please include the docket number for this document (USCG-2015-0090) and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number (USCG-2015-0090) in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this document.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8 ½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing comments and documents: To view comments, go to <http://www.regulations.gov>, type the docket number (USCG-2015-0090) in the "SEARCH" box and click "SEARCH." Click on "Open Docket Folder" on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act: Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008, issue of the Federal Register (73 FR 3316).

Background and Purpose

46 CFR 10.302 contains the medical standards that merchant mariners must meet prior to being issued a merchant mariner credential (MMC). In cases where the mariner does not meet the medical standards in 46 CFR 10.302, waivers may be granted when the Coast Guard determines that extenuating circumstances warrant special consideration. See 46 CFR 10.303. Current Coast Guard guidance in Enclosure (3) to Navigation and Vessel Inspection Circular 04-08, *Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials* (NVIC 04-08), which is available at <http://www.uscg.mil/hq/cg5/nvic/pdf/2008/NVIC%2004-08%20CH%201%20with%20Enclosures%2020130607.pdf>), states that the conditions of cardiomyopathy, diabetes mellitus,

narcolepsy and obstructive sleep apnea¹ require further review. The same guidance publishes the "recommended evaluation data" that should be submitted for each condition; however it does not specify the medical criteria that the Coast Guard will consider in evaluating whether the risks associated with these conditions are low enough to warrant a medical waiver.

Since the issuance of NVIC 04-08 on September 15, 2008, there have been several instances where mariners sought waivers for these conditions. In some cases, mariners with these conditions were granted waivers; in other cases, the conditions were deemed an unacceptable risk and medical certification was denied. Published guidance on the criteria that will be used in determining whether an applicant's medical condition warrants a medical waiver will support Coast Guard efforts to consistently evaluate merchant mariners with these conditions and assess whether the risk associated with an applicant's medical condition is sufficiently mitigated to warrant a medical waiver under 46 CFR 10.303.

¹ Enclosure (3) to Navigation and Vessel Inspection Circular 04-08, Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials, Item number 179, specifies that sleep apnea and other sleep disorders are subject to further review. Obstructive sleep apnea (OSA) is one specific type of sleep apnea and is, therefore, subject to further review under the same item number.

Under the proposed policy, a medical waiver will be required for the conditions of cardiomyopathy, sleep apnea, and diabetes mellitus.

In determining whether a mariner having one of the aforementioned conditions warrants a medical waiver under 46 CFR 10.303, the Coast Guard seeks public input on whether the Coast Guard should consider the following specific medical documentation and medical criteria:

I. NVIC 04-08, Condition # 77: Cardiac decompensation or cardiomyopathy. Individuals with these conditions may be denied medical certification unless they meet the criteria for a medical waiver.

1. Submit a cardiology consultation, nuclear exercise stress test, echocardiogram and 24-hour Holter monitor.
2. Criteria for consideration for a waiver include: a left ventricular ejection fraction of $\geq 35\%$, no symptomatic or clinically significant heart failure in the past 2 years (must be New York Heart Association Class I), absence of significant ischemia on stress testing, exercise capacity of ≥ 8 METs, no history of syncope or ventricular arrhythmia in the past three years; and the written opinion of the treating cardiologist or electrophysiologist supports low risk for sudden death, ventricular arrhythmia, adverse cardiac event and sudden incapacitation based upon objective testing and standard evaluation tools.
3. **Note:** Individuals with cardiomyopathy who have had an implantable cardioverter defibrillator (ICD) placed, will be evaluated under the criteria for condition #81, Anti-tachycardia devices or implantable

defibrillators.² Individuals with cardiomyopathy who have been advised to undergo placement of an ICD by their cardiologist, but have failed to comply, do not meet the low risk criteria for consideration for a medical waiver. These individuals may be denied medical certification.

Justification:

The Coast Guard recognizes that there is significant clinical variation within the population of individuals with cardiomyopathy, and that not all individuals with cardiomyopathy carry the same risks of sudden incapacitation or sudden death. These criteria seek to discern those individuals with cardiomyopathy who have factors that mitigate their risk, and who have prognostic indicators suggestive of a low risk of sudden incapacitation or adverse cardiac event.

- II. **NVIC 04-08, Condition # 193:** Diabetes mellitus treated with insulin or with history of diabetic ketoacidosis (DKA). Individuals with this condition may be denied medical certification unless they meet the criteria for a medical waiver:

² NVIC 04-08 Condition #81, Anti-tachycardia devices or implantable cardioverter defibrillators directs that conditions requiring use of these devices are "generally not waiverable." Enclosure (7) to NVIC 04-08 contains the criteria for consideration for a medical waiver for conditions requiring use of these devices. The criteria are summarized as follows: (1) The applicant does not have a diagnosis of a cardiac channelopathy affecting the electrical conduction of the heart (to include Brugada syndrome, Long QT syndrome, etc.); (2) The applicant does not have a prior history of ventricular fibrillation or episodes of sustained ventricular tachycardia within the last three years; (3) The ICD or anti-tachycardia device was implanted more than three years ago; (4) The ICD has not fired nor has the applicant required anti-tachycardia pacing therapy within the last three years; (5) There are no additional risk factors for inappropriate shock such as uncontrolled atrial fibrillation; (6) The applicant's left ventricular ejection fraction is greater than 35% with a steady or improving trend; (7) There is no history of any symptomatic or clinically significant heart failure in the past two years; (8) There is no evidence of significant reversible ischemia on myocardial perfusion imaging exercise stress testing; (9) The applicant's exercise capacity on formal stress testing (using standard Bruce Protocol) is greater than or equal to the 8 METs (metabolic equivalents); (10) The applicant's treating cardiologist or electrophysiologist provides a written assessment of the individual that supports a determination that the mariner is at low risk for future arrhythmia, adverse cardiac event or sudden incapacitation based upon objective testing and standard evaluation tools; (11) The applicant does not have any other medical conditions which may alone, or in combination with an ICD or anti-tachycardia device, affect the mariner's fitness.

1. Submit an evaluation from the treating physician documenting interval history and two current glycated hemoglobin (HbA1c) levels separated by at least 90 days, the most recent of which is no more than 90 days old. An ophthalmology consultation may be required. Graded exercise testing may be required.
2. If the evaluation of the treating physician supports good compliance with the treatment regimen, the absence of recent, severe hypoglycemic episodes³, and the absence of impairing diabetic complications, then mariners with a consistent pattern of HbA1c levels of less than or equal to 10% may be considered for a waiver, with annual reporting requirements.
3. Mariners with HbA1c levels greater than 10% are generally not considered for a waiver unless extenuating circumstances confirm temporary irregularity due to acute illness, medication interaction, or other short-term occurrence that is not likely to recur.

Justification:

Although poorly controlled diabetes can lead to long term diabetic complications, the consequences of hypoglycemia pose an immediate threat of sudden incapacitation with a greater risk to public and maritime safety.

III. NVIC 04-08, Condition #194: Diabetes requiring oral medication.

1. Submit an evaluation from the treating physician documenting interval history and two current glycated hemoglobin (HbA1c) levels separated by at least 90 days, the most recent of which is no more than 90 days old. Ophthalmology consultation may be required. Graded exercise testing may be required.
2. If the evaluation of the treating physician supports good compliance with the treatment regimen, the absence of recent, severe hypoglycemic(*) episodes, and the absence of impairing diabetic complications,

³Recent, severe hypoglycemic episode is an episode of hypoglycemia within the prior 12 months resulting in seizure, loss of consciousness or altered consciousness, or requiring assistance from another person for treatment.

then mariners with a consistent pattern of HbA1c levels of less than 8% may be considered for a waiver with biennial (every two years) reporting requirements; and mariners with HbA1c levels between 8% - 10% inclusive may be considered for a waiver, with annual reporting requirements.

3. Mariners with HbA1c levels of greater than 10% are generally not considered for waiver unless extenuating circumstances confirm temporary irregularity due to acute illness, medication interaction, or other short-term occurrence that is not likely to recur.

Justification:

Although poorly controlled diabetes can lead to long term diabetic complications, the consequences of hypoglycemia pose an immediate threat of sudden incapacitation with risk to public and maritime safety.

IV. NVIC 04-08, Condition # 179: Obstructive Sleep Apnea, Central Sleep Apnea, Narcolepsy, Periodic Limb Movement, Restless Leg Syndrome or other sleep disorders.

1. Submit all pertinent medical information, including sleep studies and a status report. If surgically treated, please submit a post-operative polysomnogram to document cure.
2. **Narcolepsy, idiopathic hypersomnia and other hypersomnias of central origin:** Due to the significant risk of sudden and unpredictable incapacitation of individuals who have these conditions, narcolepsy, idiopathic hypersomnia and other hypersomnias of central origin are considered disqualifying. Additionally, the Coast Guard does not consider the conditions of narcolepsy, idiopathic hypersomnia, or other hypersomnias of central origin, as low enough risk to warrant consideration for a medical waiver.
3. **Obstructive Sleep Apnea (OSA):**
 - A. Medical waivers for OSA require submission of an annual sleep specialist evaluation that documents treatment efficacy, the patient's treatment compliance

and an assessment for symptoms of daytime sleepiness. If treated with CPAP/BiPAP, the evaluation should include a compliance information report from the positive airway pressure device that covers the preceding 12 months. For OSA treated by other means, submit a polysomnogram demonstrating the effectiveness of the alternative therapy.

B. For purposes of receiving or maintaining a medical waiver, minimum compliance with positive airway pressure therapy is defined as:

- i) Proper use of the CPAP/BiPAP device for at least four hours per night (or per major sleep period) during all major sleep periods while acting under the authority of the mariner credential, and
- ii) Proper use of the CPAP/BiPAP device for at least four hours per night (or per major sleep period) on at least 70% of all nights (or major sleep periods).

Authority

This document is issued under the authority of 5

U.S.C. 552(a) and 46 U.S.C. 7101 et seq.

Dated: February 10, 2015.

J. C. Burton,
Captain, U.S. Coast Guard,
Director of Inspections & Compliance.

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